UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

NEWTON'S PHARMACY, INC., individually and on behalf of those similarly situated, Plaintiffs, v. PROCTER & GAMBLE COMPANY; KENVUE, INC.; MCNEIL CONSUMER HEALTHCARE; RECKITT & BENCKISER LLC; and GLAXOSMITHKLINE, LLC, Defendants.	Case No. _____ **JURY TRIAL DEMAND**

CLASS ACTION COMPLAINT

Plaintiff Newton's Pharmacy Inc., ("Plaintiff"), brings this action individually and on behalf of all others similarly situated, upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters based on the investigation of counsel, allege as follows:

INTRODUCTION

1. This case arises from the Plaintiff's and putative class members' purchase of ineffective over-the-counter ("OTC") medications drugs that were manufactured, promoted, marketed, distributed and sold as providing nasal decongestant effects when the active ingredient in those medications, phenylephrine ("PE") has failed to demonstrate any pharmacological benefit to treat that symptom beyond what would be offered by a placebo when administered orally. On September 11, 2023, the Nonprescription Drug Advisory

Committee ("NDAC") to the Food and Drug Administration issued a report concluding that oral OTC medications using PE as the active ingredient to treat nasal congestion had no effect beyond placebo in treating that condition. At the time the NDAC issued this report the Plaintiff and thousands of other similarly situated retail pharmacies across the country had hundreds of these OTC medications stocked on its shelves that immediately lost value. The FDA is now considering whether to pull these products from the market and retail pharmacies are now stuck having to decide whether to pull these products from its shelves, cancel wholesaling contracts, or impose disclaimers that the manufacturers of these products have failed to include on their own products.

2. The case involves some of the most well-known consumer facing brands in the OTC medication market including Advil, Tylenol, Dayquil, Nyquil, TheraFlu, Sudafed and many others. Throughout this Complaint the Defendants' OTC products containing orally administered PE as the active ingredient to provide nasal decongestant relief shall be referred to as the "**Ineffective Decongestant Products**."

3. Plaintiff seeks damages and equitable relief, individually and on behalf of other class members, for Defendants' improper marketing sales tactics that have resulted in retail pharmacy loss of sales and other pecuniary harm as a result of Defendant's unfair and deceptive practices.

PARTIES

A. Plaintiff

4. Plaintiff Newton Pharmacy Inc., is an Arkansas corporation with its principal place of business in Russellville, Arkansas. Plaintiff is a licensed retail pharmacy and has been in the business of providing both prescription and OTC medications along with other personal

and household goods to members of the general public for over fifty years. As part of its routine business, Plaintiff stocked on its shelves the Ineffective Decongestant Products made by the Defendants. Plaintiff purchases these products through wholesalers with the intent to resell them to customers within the store. Plaintiff paid money for Defendants' Ineffective Decongestant Products and as a result of the Defendant's false representations that these products provided nasal decongestant relief, and now Plaintiff has a large inventory of product whose resale value has been impaired. Plaintiff has also had to devote time and resources to establishing an appropriate cold and flu therapy inventory now that customers are beginning to understand that traditional brands using oral PE they relied upon to provide nasal decongestant relief do not actually treat such a symptom.

B. Defendants

5. Defendant The Procter & Gamble Company ("P&G") is an Ohio corporation with its principal place of business and headquarters located at One Procter & Gamble Plaza in Cincinnati, Ohio. At all times material to this case, P&G has been engaged in the manufacturing, sale, and distribution of OTC medications containing PE that have been falsely marketed as providing nasal decongestant relief when in fact PE provides no such relief. GSK markets, promotes, and distributes Ineffective Decongestive Products containing PE through the Vicks, Dayquil, Nyquil, and FluTherapy brands.

6. Defendant Kenvue Inc. ("Kenvue") is an American consumer health company and formerly the consumer division of Johnson & Johnson ("J&J"). Kenvue is headquartered in New Jersey. At all relevant times Kenvue and its predecessor J&J has been engaged in the manufacturing, sale, and distribution of OTC medications containing PE that have been falsely marketed as providing nasal decongestant relief when in fact PE provides no such relief.

Kenvue and previously J&J markets, promotes, and distributes Ineffective Decongestive Products containing PE through the Sudafed PE and Benadryl brands.

7. Defendant McNeil Consumer Healthcare ("McNeil") is a wholly owned subsidiary of Kenvue with headquarters in Pennsylvania. At all times material to this case, McNeil has been engaged in the manufacturing, sale, and distribution of OTC medications containing PE that have been falsely marketed as providing nasal decongestant relief when in fact PE provides no such relief. McNeil markets, promotes, and distributes Ineffective Decongestive Products containing PE through the Tylenol Cold + Flu brand.

8. Defendants Reckitt & Benckiser LLC ("Reckitt") is a Delaware limited liability corporation with its headquarters and principal place of business located in Parsippany, New Jersey. At all times material to this case, Reckitt has been engaged in the manufacturing, sale, and distribution of OTC medications containing PE that have been falsely marketed as providing nasal decongestant relief when in fact PE provides no such relief. Reckitt markets, promotes, and distributes Ineffective Decongestive Products containing PE through the Mucinex brand.

9. Defendant GlaxoSmithKline LLC ("GSK") is a Delaware corporation with its principal place of business in Philadelphia, Pennsylvania. At all times material to this case, GSK has been engaged in the manufacturing, sale, and distribution of OTC medications containing PE that have been falsely marketed as providing nasal decongestant relief when in fact PE provides no such relief. GSK markets, promotes, and distributes Ineffective Decongestive Products containing PE through the Theraflu, Advil, and Robitussin brands.

10. Collectively the P&G, Kenvue, Reckitt, and GSK shall be collectively referred

to throughout the complaint when appropriate as "Defendants."

JURISDICTION AND VENUE

11. This Court has original jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of each Defendant, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

12. This Court has personal jurisdiction over Defendants because each Defendant has sufficient minimum contacts in this state, and because each Defendant has otherwise intentionally availed itself of the markets within this state through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

13. Venue is proper in this District because the claims alleged in this action accrued in this District and each Defendant regularly transacts its affairs in this District.

14. Each Defendant is subject to the personal jurisdiction of this Court because the Defendants conduct business within this state, maintain and carry out continuous and systematic contacts within this state and this judicial District, regularly transacts business within this state and this judicial District, and regularly avails themselves of the benefits of their presence in this state and this judicial District.

FACTUAL ALLEGATIONS

A. The Big Business Of Nasal Decongestants

15. The market for drugs purported to relieve congestion is over $2 billion per year and includes at least 250 products.

16. One of the two leading ingredients, only phenylephrine ("PE") is sold over the

counter ("OTC"). The other leading ingredient, pseudoephedrine, is effective but is usually sold behind the counter from locked containers, and consumers are limited in the number they can buy. As a result, PE drugs are more popular and account for approximately 80% of the $2 billion annual market.

17. These medicines are most often used to treat the common cold. According to the American Lung Association, approximately 200 different viruses can cause cold like symptoms which often leads to runny nose, congestion, sneezing.

18. In the United States, colds account for more visits to the doctor than any other single condition. Adults get an average of two to four colds per year, mostly between September and May. In the United States it is estimated that people in the United States suffer 1 billion colds annually.

19. There are no antiviral medications available for treating the common cold and instead the vast majority of patients rely on products to provide symptom relief. OTC medications are a common form patients seek to receive symptom relief for the common cold.

20. This stunning demand has caused companies to leverage the OTC space in order to provide ostensible symptom relief for the millions of Americans suffering this common ailment.

21. When OTC medications containing pseudoephedrine began receiving adding regulatory scrutiny (due to their propensity to make it into the illegal drug market), companies began marketing efforts to drive consumers to products containing PE.

22. PE and pseudoephedrine have different mechanism of action. PE is a specific alpha-1 adrenergic receptor agonist that works by temporarily constricting blood vessels. By

contrast, pseudoephedrine is a relatively less selective agonist that acts on both alpha and beta-adrenergic receptors and is therefore more lipophilic than PE and is more accessible to the central nervous system because it crosses the blood-brain barrier. As a result, pseudophedrine when taken orally does not metabolize at the same rate as PE making it more bioavailable when administered orally when compared to PE. Defendants are well aware of the mechanisms of action between pseudophedrine and PE and the different metabolic rates for each ingredient.

B. Defendants Marketed OTC Medications Containing PE As A Decongestant

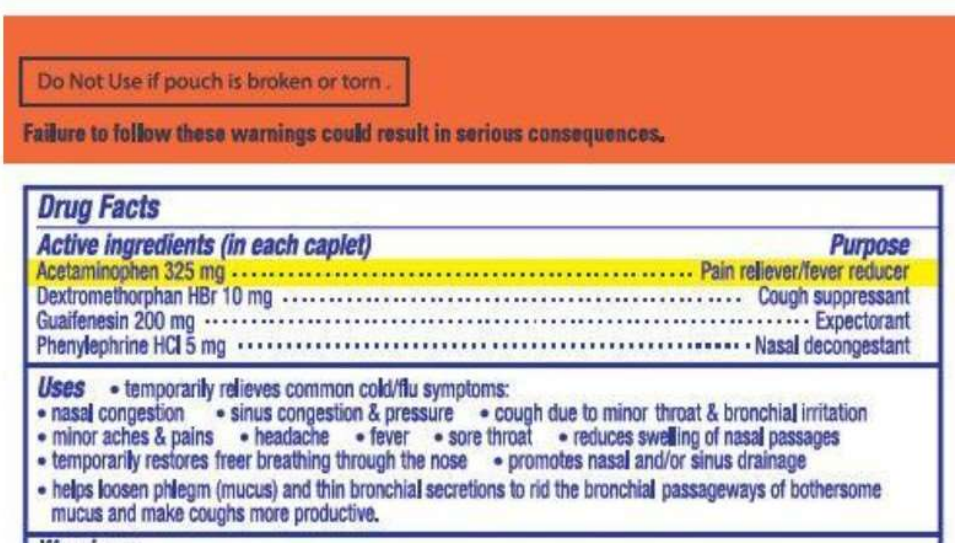
23. P&G market the following OTC medications as a decongestant: Vicks Nyquil Severe Cold and Flu, Vicks NyQuil Sinex, Vicks Dayquil Severe Cold and Flu, Vicks Sinex Severe, Vicks Flu Therapy Night Severe Cold and Flu. On its website, P&G makes the following representations regarding PE:

Vicks Products for Nasal Congestion Relief

Nasal congestion, also known as stuffy nose, is when the lining of the nasal cavity becomes inflamed and swollen, which can cause mucus to build up. Nasal congestion is typically caused by one of two things—a viral infection (like a cold or flu) or allergies (often triggered by dust, pet dander, and more). Learn more about nasal congestion.

To relieve your nasal congestion symptoms, look for an OTC medicine with a decongestant like Phenylephrine or Oxymetazoline. Decongestants constrict enlarged blood vessels to shrink the swollen nasal tissues causing your stuffy nose. The ingredients label on the back of Vicks products will give the name of the active ingredient, and identify what type of active ingredient it is, to help clear up any confusion on the shelf.

24. P&G's product package all indicate that PE provides decongestant relief. As just one example, here is the product packaging for Dayquil Severe Fold and Flu:



Do Not Use if pouch is broken or torn .

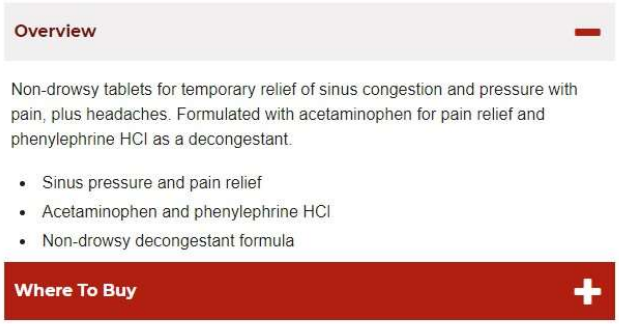
Failure to follow these warnings could result in serious consequences.

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses • temporarily relieves common cold/flu symptoms:
• nasal congestion • sinus congestion & pressure • cough due to minor throat & bronchial irritation
• minor aches & pains • headache • fever • sore throat • reduces swelling of nasal passages
• temporarily restores freer breathing through the nose • promotes nasal and/or sinus drainage
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

25. Kenvue, formerly J&J, and McNeil through their consumer brands market the following OTC medications as decongestants: Sudafed PE, Benadryl Allergy Plus Congestion, and Tylenol Cold + Flu. On its website for Sudafed OE, J&J makes the following representations:



26. GSK market the following OTC medications as decongestants: Advil Sinus Congestion and Pain and Robitussin. On its website GSK makes the following representations:

Advil Sinus Congestion & Pain See Drug Facts

Advil Sinus Congestion & Pain combines the speed and strength of Advil and a proven nasal decongestant for fast, effective relief of sinus pressure and congestion associated with colds. Though mucus can contribute to the stuffed up feeling, nasal congestion is the swelling of the tissues in the nose and sinuses caused by inflammation. Advil Sinus Congestion & Pain re-opens your airways by constricting the blood vessels in your nose and sinuses.

Advil Sinus Congestion & Pain also treats the pain associated with colds. The philosophy behind Advil Sinus Congestion & Pain is that cold-sufferers who treat only nasal congestion or the pain associated with it really only address half the problem. Both pain and congestion are major symptoms of colds so it just makes sense to treat them both with just one tablet. Get fast, powerful relief with Advil Sinus Congestion & Pain.

27. PE is listed as the active ingredient providing the "decongestant" effect marketed in all of these products.

28. Each Defendant makes similar claims that PE works as the active nasal decongestant ingredients in these numerous consumer facing brands. Each Defendant promises, and expects consumers to rely upon these promises, that these products contain active ingredients that will aid to relieve the symptoms of nasal congestion.

29. Defendants know that consumers rely upon decongestant relief when searching for an OTC medication to provide symptom relief for the common cold and other ailments and illnesses causing nasal congestion and directly market their products as providing this relief. In fact, in many of the product packaging for cold and flu OTC medications "nasal congestion" is often the first symptom listed that these OTC medications treat. Defendants do this because they know when suffering from cold and flu and other similar ailments nasal congestion is one of the key symptoms consumers of these OTC medications seek to relieve.

30. Defendants marketing and promotional efforts created an expectation in consumer's minds that PE was an effective decongestant and it created demand for these types of products. As a result, Plaintiff and other similarly situated retail pharmacies took steps to ensure

that they could meet this consumer demand by purchasing these products and devoting shelf space to these products. As demand was constant retail pharmacies needed to ensure an adequate supply of these medications for fear of losing customers to other competitors if these products were not in stock on an as needed basis.

31. All Defendants either in websites, advertisements, product packaging or other messages communicated to the public that all Ineffective Decongestant Products would help alleviate nasal congestion. For all Ineffective Decongestant Products these statements were false or misleading and caused customers of Plaintiff and the putative classes to believe that these products would be effective in providing relief from nasal congestion. Customer relied upon these representations and would not have purchased the Ineffective Decongestant Products had they been aware that PE simply was not effective as a nasal decongestant. Retail pharmacies would not have stocked these products, would not have entered into wholesaling contracts to secure a supply of these products, and would not have devoted shelf space to these products had they known of this fact.

C. PE Is Simply Not A Decongestant When Administered Orally

32. Unfortunately for consumers (but known to Defendants), phenylephrine does not work when taken orally to relieve congestion. This is because once metabolized by the stomach the bioavailable amount of PE available is around 1%, an insufficient amount to actually result in a pharmacological effect.

33. The NDAC conducted a meta-review of the original data used by the FDA to approve PE as a nasal decongestant and the data from studies conducted after the initial FDA review. The conclusion of the NDAC could not be more clear: PE when used orally does not work

as a decongestant. Specifically, the NDAC found:

> As a result of our evaluation, we believe that the new efficacy data far outweigh the data provided to the Agency as part of the original Panel review. These results suggest that: 1) oral PE at monographed dosages is not effective as a decongestant (i.e., in the face of the new data, the original data are likely not sufficient to support a GRASE determination), 2) oral doses up to 40 mg would also not be effective, 3) finding an effective oral dose that is also safe is not feasible (meaning that doses higher than 40 mg would need to be explored but would also not be safe to study due to effects on blood pressure), and 4) an appropriate dosing interval for oral PE has not been established (meaning that, based on the PK data, an every-4-hour dosing interval is likely too long). Therefore, in addition to lack of efficacy, there may be no path to evaluating higher doses of oral PE as a nasal decongestant.

34. The NDAC reached this conclusion through an exhaustive review of the available studies including studies from 2015-2017 showing that PE when taken orally at the dosages available in OTC medications resulted in no greater effect on decongestants than a placebo. The NDAC Briefing Document published on September 11, 2023 on the oral efficacy of PE as a decongestant is attached as **Exhibit A**.

35. The FDA is now considering banning PE from oral medication, which would result in pulling hundreds of products containing PE from shelves. Since the FDA panel's conclusion came out, prices for oral medication containing PE have plummeted and consumers are looking elsewhere for the decongestant relief Defendants promised PE would deliver.

D. Defendants Knew PE Is Not Effective As A Decongestant.

36. Defendants are large corporations with dedicated units devoted to reviewing and commenting on studies that affect their products.

37. As a result, Defendants knew of the studies cited by the NDAC and specifically were aware of the studies from 2015-present that demonstrate PE is not an effective decongestant.

38. Nevertheless, Defendants continued to promote to the public that OTC

medications containing PE and that would be administered orally were effective as a "decongestant."

E. Retail Pharmacies Have Been Injured By Defendants' Misrepresentations About the Effectiveness of the Ineffective Decongestant Products

39. The FDA originally designated PE as safe and effective for use as a decongestant in 1976 and it became a common ingredient in multidrug cold medications like DayQuil and Sudafed PE over the course of the past 50 years. When originally greenlighted relied upon a review of 14 studies (12 unpublished and two published) from pharmaceutical companies.

40. Retail pharmacies like Plaintiff are pharmacies where drugs are compounded, dispensed, stored or sold and where prescriptions are filled or dispensed to the general public. Foot traffic is an important part of retail pharmacy business and the common cold and flu are one of the common drivers of foot traffic within retail pharmacies as customers come into obtain both prescription and OTC medications to relieve cold and flu symptoms.

41. Retail pharmacy is a highly competitive space in the provision of healthcare in this country and the industry has seen a dramatic amount of consolidation. Additionally, According to a report by the Assistant Secretary for Planning and Evaluation (ASPE), there has been a change in the location where Americans receive their drugs. Between 2016 and 2021, there has been a 95% increase in the number of Americans receiving their drugs from home health care. Additionally, there has been a 45% increase in drugs received from clinics and a 35% increase from mail-order pharmacies over the same period. On the other hand, there has been a decline in drugs received from long-term facilities (17%), federal facilities (9%), and independent pharmacies (5%). The shift towards home health care, clinics, and mail-order pharmacies can be attributed to the increasing consumer preference for over-the-counter (OTC) drugs and the

growing demand for home delivery of medications, which is expected to contribute to the growth of the U.S. pharmacy market in the coming years but is expected to add to the decline in market share for independent retail pharmacies like Plaintiff.

42. To meet these market conditions, pharmacies in the U.S. offer a variety of patient-care services and implement strategies to increase medication sales. Pharmacies offer their customers a wide range of services. For example, 84% of pharmacies provide flu immunizations, 80% provide non-flu immunizations, 53% offer blood pressure monitoring, and 30% offer diabetes education.

43. Ensuring adequate supply of routine OTC medications commonly used by members of the general public is a key part of the retail pharmacy business because it helps drive foot traffic and ensure customers come into stores. These market pressures require pharmacies like Plaintiff to carry a variety of OTC medication and as a result Plaintiff purchased through wholesalers the Ineffective Decongestant Products and provided a large amount of shelf space for the sale of these products because customers often look for these types of well marketed and promoted OTC medications to treat symptoms associated with the common cold and flu.

44. When the NDAC announced the results of its review and its conclusion that PE when administered orally was simply not an effective nasal decongestant, contrary to what Defendants have been telling Plaintiff, retail pharmacies, and consumers for years, the value and desirability of the Ineffective Decongestant Products plummeted. As a result, Plaintiff and other retail pharmacies now have a surplus of product whose value has been impaired, may eventually be removed from the market altogether, and face the prospect of taking either a partial or total loss on their purchases.

45. Worse because the FDA has not yet pulled these products from the market and because not every consumer is aware of the recent disclosures, retail pharmacies are having to devote significant resources to educating customers about these developments. This process is hindered because even today on their websites, advertisements, and product labels, the Defendants continue to misrepresent the Ineffective Decongestant Products as being effective in treating nasal congestion.

46. Retail pharmacies like Plaintiff have purchased virtually all available OTC medications marketed, distributed and sold by the Defendants containing PE as the active ingredient purportedly to treat nasal decongestant. Retail pharmacies are therefore caught in a difficult situation as to removing these products from product shelves altogether and risk losing foot traffic as customers go to other sources or continue to purchase these products and educate customers about the ineffectiveness of these products to treat the conditions Defendants claim they treat.

CLASS ALLEGATIONS

47. Plaintiffs bring this action pursuant to Rules 23(a), 23(b)(2), 23(b)(3), and 23(c)(4) of the Federal Rules of Civil Procedure on behalf of themselves and all others similarly situated. Plaintiffs seek to represent the following Classes:

> All retail pharmacies that purchased oral nasal decongestant containing phenylephrine manufactured by Defendants (the "Nationwide Class").
>
> All retail pharmacies who purchased an oral nasal decongestant containing phenylephrine manufactured by Defendants in the State of Arkansas (the "Arkansas Class").

48. Excluded from the Classes are any retail pharmacies that manufacturer or promote

their own version of OTC medications containing PE as the active ingredient to treat nasal decongestants and Defendants, and any of the Defendants' members, affiliates, parents, subsidiaries, officers, directors, employees, successors, or assigns; the judicial officers, and their immediate family members; and Court staff assigned to this case. Plaintiffs reserve the right to modify or amend the Class definition, as appropriate, during the course of this litigation. This action has been brought and may properly be maintained on behalf of the Classes proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

49. Certification of Plaintiffs' claims for classwide treatment is appropriate because Plaintiffs can prove the elements of their claims using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

50. **Numerosity**: Rule 23(a)(1): The members of the Classes are so numerous and geographically dispersed that individual joinder of all Class Members is impracticable. Plaintiffs are informed and believe that there are hundreds of thousands of members of the Classes based on the size of the market for decongestant products and Defendants' share of that market, but the precise number of Class members is unknown to Plaintiffs.

51. **Commonality and Predominance**: Rule 23(a)(2) and (b)(3): This action involves common questions of law and fact which predominate over any questions affecting individual Class members, including, without limitation: a. When Defendants knew that phenylephrine was ineffective as a decongestant; b. Whether Defendants sold Ineffective Decongestant Products as effective; c. What measures Defendants took to conceal the true nature of their Ineffective Decongestant Products; d. Defendants' duty to disclose the true nature of their Ineffective Decongestant Products; e. Whether Plaintiffs and the other Class members overpaid for

Defendants' Ineffective Decongestant Products; and f. Whether Plaintiffs and the other Class members are entitled to equitable and injunctive relief.

52. **Typicality**: Rule 23(a)(3): Plaintiffs' claims are typical of the other Class Members' claims because, among other things, all Class members were comparably injured through Defendants' wrongful conduct as described above. Plaintiffs suffered damages as a direct proximate result of the same wrongful practices in which Defendants engaged.

53. **Adequacy**: Rule 23(a)(4): Plaintiffs are adequate Class Representatives because their interests do not conflict with the interests of the other members of the Classes they seek to represent; Plaintiffs have retained counsel competent and experienced in complex class action litigation; and Plaintiffs intend to prosecute this action vigorously. Plaintiffs and their counsel will fairly and adequately protect the Class's interests.

54. **Superiority**: Federal Rule of Civil Procedure 23(b)(3): A class action is superior to any other available means for the fair and efficient adjudication of this controversy and no unusual difficulties are likely to be encountered in managing this class action. The damages or other financial detriment suffered by Plaintiffs and the other Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendants, so it would be impracticable for the members of the Classes to individually seek redress for Defendants' wrongful conduct. Even if Class members could afford individual litigation, such litigation creates a potential for inconsistent or contradictory judgments. It increases the delay and expense to all parties and the court system. By contrast, a class action is suited and intended to manage such difficulties and provide the benefits of uniform and common adjudication, economy of scale, and comprehensive supervision.

55. **Declaratory Relief**: Federal Rule of Civil Procedure 23(b)(2): Defendants have acted or refused to act on grounds generally applicable to Plaintiffs and the other members of the Classes, thereby making declaratory relief appropriate, with respect to each Class as a whole.

CLAIMS

COUNT I
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(All Defendants)

56. Plaintiffs repeat and reallege the foregoing as if fully set forth herein.

57. Plaintiffs bring this claim on behalf of the Nationwide Classes or, in the alternative, the State Classes (the "Class," for purposes of this Count).

58. Defendants were at all times a "merchant" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

59. The Ineffective Decongestant Products are and were "goods" within the meaning of Article 2 of the U.C.C., as codified under applicable law

60. Defendants were obligated to provide Plaintiffs and the other Class members Ineffective Decongestant Products that were of merchantable quality, were reasonably fit for the purpose for which they were sold, and conformed to the standards of the trade.

61. Defendants impliedly warranted that those drugs were of merchantable quality and fit for that purpose.

62. Defendants breached their implied warranties, because their Ineffective Decongestant Products were not of merchantable quality or fit for their ordinary purpose.

63. Defendants' breaches of implied warranties were a direct and proximate cause of Plaintiffs' and the other Class members' damages.

COUNT II
FRAUD BY OMISSION OR CONCEALMENT
(All Defendants)

64. Plaintiffs repeat and reallege the forgoing as if fully set forth herein.

65. Plaintiffs bring this claim on behalf of the Nationwide Classes or, in the alternative, the State Classes (the "Class," for purposes of this Count).

66. Defendants intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality or grade of the PE Drugs. Due to their fraudulent conduct, Plaintiffs and the other Class members have suffered actual damages.

67. Defendants knew that phenylephrine is ineffective at safe dosages when consumed orally.

68. Defendants were obligated to inform Plaintiff and the other members of the Class of the effectiveness of phenylephrine due to their exclusive and superior knowledge of the Decongestant Products.

69. Plaintiffs and other Class members also expressly reposed a trust and confidence in Defendants because the nature of their dealings as a healthcare entity and with Plaintiffs and other members of the Class as their consumers.

70. Plaintiffs and the other Class members would not have purchased the Decongestant Products but for Defendants' omissions and concealment of material facts regarding the nature and quality of the Decongestant Products and existence of the Decongestant Products, or would have paid less for the Decongestant Products.

71. Defendants knew their concealment and suppression of material facts was false and misleading and knew the effect of concealing those material facts.

72. Defendants acted with malice, oppression, and fraud.

73. Plaintiffs and the other Class members reasonably relied on Defendants' knowing, affirmative, and active false concealment and omissions. As a direct and proximate result of Defendants' omissions and active concealment of material facts regarding the Decongestant Products, Plaintiffs and the other Class members have suffered actual damages in an amount to be determined at trial.

COUNT III
FALSE ADVERTISING UNDER THE LANHAM ACT
15 U.S.C. § 1125(A)
(All Defendants)

74. Plaintiffs repeat and reallege the foregoing as if fully set forth herein.

75. Plaintiffs bring this claim on behalf of the nationwide Class or, in the alternative, the State Classes (the "Class," for purposes of this Count).

76. Defendants made and make false and misleading statements regarding the descriptions of fact and/or representations of fact in commerce regarding the nature, characteristics, qualities, and/or origin of the Ineffective Decongestant Products. Such false and misleading statements include claiming that PE in oral OTC medications acts as a "decongestant" and/or that the Ineffective Decongestant Products were effective in treating the symptoms of nasal congestion.

77. These representations constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

78. These misrepresentations are made in interstate commerce and in connection with the Defendants' goods, which are sold, marketed, and distributed in interstate commerce. Defendants make these misrepresentations in advertising, product packaging, websites throughout the United States.

79. These misrepresentations are false or misleading, confusing and deceptive.

80. These misrepresentations deceived or had the tendency to deceive Plaintiff, the Class, and their customers. Among other things these misrepresentations cause confusion within the general public and Plaintiff and the Class' customers by duping them into believing that the Ineffective Decongestant Products are effective in treating nasal congestion. Customers came to believe these products were effective and required and expected retail pharmacies like Plaintiff and the Class to carry these products. Had Plaintiff and the Class not carried these products customers would have looked elsewhere for these products because of Defendants misrepresentations caused customers to believe the Ineffective Decongestant Products could treat nasal congestion.

81. Defendants have acted in bad faith and have willfully and deliberately committed the foregoing acts with knowledge that the information is intended to deceive or confuse customers.

82. Retail pharmacies like Plaintiff and the Class have been injured and are likely to be injured as a result of Defendants' false and misleading claims. These injuries include paying more for the Ineffective Decongestant Products than they otherwise would have, devoting shelf space to these products that could have been devoted to other products that actually worked, incurring the initial costs to stock the product and then costs associated with both removing the product from the shelves and re-stocking with different effective products, having inventory at the time of the NDAC report that could not be sold or had to be sold at a loss, devoting resources to educate customers on Defendants' misleading misrepresentations, and losing customer trust and loyalty because Plaintiff and the Class stocked and sold OTC medications that could not and did not deliver the relief to customers that Defendants promised.

83. Retail Pharmacies like Plaintiff and the Class are within the zone of interest to be

protected by the Lanham Act as pharmacists and staff of these retail establishments are often called to answer questions and concerns patients have when seeking to alleviate common symptoms associated with the common cold and flu and other ailments like nasal congestion. Retail pharmacies like Plaintiff and the Class are expected to carry these OTC medications and customers have come to trust retail pharmacies to carry and provide these types of medications when patients and customers need them.

84. Accordingly, Plaintiff and the Class have suffered and will likely suffer injury to their commercial interest in their business reputation as well as injury to their commercial interests in sales and future sales as a result of Defendants' misrepresentations. These misrepresentations have a chilling effect on the ability to credibly engage in the pharmacy business and discourage customers from seeking purchases of other goods and services that in fact would provide the nasal congestion relief that Defendants promised the Ineffective Decongestant Products offered.

85. Plaintiffs and the Class are entitled to recover their actual damages and costs of this action in an amount to be proven at trial and such damage should be trebled as allowed by 15 U.S.C. § 1117(A).

86. Plaintiff and the Class are further entitled to recover the Defendants profits, the amount of which is currently unknown, and which amount should be trebled as allowed under 15 U.S.C. § 1117(a). This is an exceptional case pursuant to 15 U.S.C. § 1117(a), and Plaintiffs and the Class are therefore entitled to recover their reasonable attorneys' fees.

COUNT IV
NEGLIGENT MISREPRESENTATION
(All Defendants)

87. Plaintiffs repeat and reallege the foregoing as if fully set forth herein.

88. Plaintiffs bring this claim on behalf of the nationwide Class or, in the alternative,

the State Classes (the "Class," for purposes of this Count).

89. Defendants had a duty to provide truthful and accurate information regarding the Ineffective Decongestant Products. Defendants had a duty to make themselves aware of the medical literature regarding PE and to track over time the medical literature regarding the efficacy of PE to treat nasal congestion when administered orally.

90. Defendants breached these duties in the following ways:

a. Misrepresenting that PE when administered orally is effective in treating nasal congestion;

b. Misrepresenting that PE when administered orally provided "decongestant" effects;

c. Misrepresenting that the Ineffective Decongestant Products was an effective treatment to alleviate nasal congestion.

d. Failing to timely learn or review the available medical literature to determine that PE when administered orally was ineffective to treat nasal congestion.

e. Failing to timely alert the FDA that the Ineffective Decongestant Products were ineffective to treat the condition of nasal congestion.

91. Additionally, Defendants made and make false and misleading statements regarding the descriptions of fact and/or representations of fact in commerce regarding the nature, characteristics, qualities, and/or origin of the Ineffective Decongestant Products. Such false and misleading statements include claiming that PE in oral OTC medications acts as a "decongestant" and/or that the Ineffective Decongestant Products were effective in treating the symptoms of nasal congestion.

92. These breaches and misrepresentations caused Plaintiff and the class harm. As a result of the breaches of duties described herein Plaintiff and the Class have product that they

cannot sell or must sell at significant discounts, must devote resources to educated customers as to the truth of PE's effectiveness to treat nasal congestion when administered orally, and loss of customer goodwill and loyalty for selling products that were ineffective to treat the conditions Defendants promised they would treat.

93. Plaintiffs and the Class are entitled to recover their actual damages and costs of this action in an amount to be proven at trial.

COUNT V
UNJUST ENRICHMENT
(All Defendants)

94. Plaintiffs repeat and reallege the foregoing as if fully set forth herein.

95. Plaintiffs bring this claim on behalf of the nationwide Class or, in the alternative, the State Classes (the "Class," for purposes of this Count).

96. It would be inequitable for Defendants to insulate themselves from liability on this unjust enrichment claim by asserting that retail sales by their retailers cuts off any relationship between the Plaintiffs and the Classes and Defendants because Plaintiffs and the other Class members cannot seek a remedy directly from Defendants' retailers based on Defendants' sale of the Decongestant Products.

97. Plaintiffs and all other Class members conferred a benefit on Defendants by purchasing Decongestant Products.

98. Defendants have been unjustly enriched in retaining the revenues derived from Class members' purchases of Decongestant Products, which retention under these circumstances is unjust and inequitable because Defendants misrepresented that Decongestant Products were effective for providing congestion relief when in fact they were not, which caused injuries to Plaintiffs and all Class members because they paid a price premium due to Defendants' deception.

Because Defendants' retention of the non-gratuitous benefit conferred on it by Plaintiffs and all Class members is unjust and inequitable, Defendants must pay restitution to Plaintiffs and the Class members for their unjust enrichment, as ordered by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the other Class members, respectfully request that the Court enter judgement in their favor and against Defendant, as follows:

A. Certification of the proposed Class with Plaintiffs as class representatives;

B. Appointment of Plaintiffs' counsel as Class Counsel;

C. Injunctive relief, including, but not limited to requiring Defendants to make full disclosure of their knowledge of the efficacy of their Ineffective Decongestant Products;

D. Disgorgement of their profits from the sales of their Ineffective Decongestant Products;

E. Damages, including punitive damages, treble damages costs, and disgorgement in an amount to be determined at trial;

F. An order requiring Defendants to pay both pre- and post-judgment interest on all amounts awarded;

G. An award of costs and attorneys' fees; and

H. Such other further relief as may be appropriate.

DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of those similarly situated, demands a trial by jury on all issues so triable.

Dated: September 27, 2023

Respectfully submitted,

By: */s/ Alyson S. Beridon*
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*Application for admission *pro hac vice* forthcoming